

**AABB Task Force to Redesign the Blood Donor Screening Questionnaire
Final Report to FDA**

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I. Introduction

The Donor History Questionnaire (DHQ) and abbreviated Donor History Questionnaire (aDHQ) are the result of an exceptional undertaking that began three years ago at the urging of the Food and Drug Administration (FDA). The goal of the project was to bring about major improvements in the blood donor screening questionnaire. To achieve this objective, the FDA advocated the formation of a multidisciplinary Task Force under the aegis of the American Association of Blood Banks (AABB). The FDA has had active representation in the process, has provided input on a consistent basis, and presented evolving Task Force ideas to the Center for Biologics Evaluation and Research (CBER).

One of the most significant aspects of this redesign effort was that by applying modern principles of survey design, the Task Force introduced a groundbreaking approach to formulating and evaluating donor screening questions. The changes the Task Force is proposing are intended to enhance blood safety by making the screening process more effective in capturing relevant blood donor qualifying information. Further, by simplifying the questions and the screening process, it is anticipated that blood donor recruitment and retention will be enhanced.

II. The Current Uniform Donor History Questionnaire (UDHQ)

The official nationwide process for conducting pre-donation screening of blood donors was initiated in 1953 by the AABB when it introduced a screening form, the Donor Record Card¹. The use of a pre-donation questionnaire has assumed increasing importance in identifying and excluding individuals with the potential for transmitting blood borne diseases. The instrument now utilized is an FDA-approved AABB document called the Uniform Donor History Questionnaire (UDHQ). The current role of the screening process, as defined by the FDA is to screen for diseases or conditions for which there are no tests, reduce the demand for detection of infectious agents by tests, reduce window period collections, and prevent collection of infectious units that might be released in error². An equally important goal is the enhancement of donor safety.

III. Difficulties with the UDHQ

While the donor screening process has indisputably played a role in advancing blood safety, especially prior to the implementation of serologic and nucleic acid tests, problems with the screening process, especially the UDHQ, have become evident. FDA blood product deviation reports reflect this. In fiscal year 2001 the FDA received almost 20,000 deviation reports. 16,000 of these were related to errors in the donor qualification process, including screening errors and failure to capture relevant information until some time after the donation process³. This is but one indication that a rigorous examination of the screening questionnaire had to be

undertaken. Other indications became obvious from a 2000 AABB survey of US blood centers, which showed that screening practices, educational materials, and questionnaires varied considerably from center to center .

A major contributing problem has been that in the past the process of formulating questions and the questions themselves have not been consistent with the principles of survey design. Specifically, the questions had not been designed with the input of survey design experts or behavioral scientists. The questions had generally not undergone a validation process, even for basic donor comprehension. Sentence structure is complex, characterized by compound and multi-item questions. Medical and scientific terms that are unfamiliar to the average individual are frequently used. The grouping of questions by topic may be understood by medical professionals, but the time intervals for which donors are required to recall information are not chronological and could be a source of confusion to donors. Collectively, these problems raise concerns about the overall efficacy of the process, particularly the sensitivity and specificity of screening questions. If comprehension and recall are not optimized, sensitivity could potentially be compromised; conversely, specificity could be affected, resulting in unnecessary deferrals.

As increased reliance has been placed on the pre-donation qualification process, numerous questions have been added to the UDHQ. It is believed that its 42-question length may serve as a disincentive to prospective donors. The requirement that even frequent donors must answer all questions for every donation has also given rise to concerns that this bedrock group of individuals could be discouraged from their continuing support of the community blood supply during these times of chronic and worsening blood shortages. An abbreviated questionnaire for this group is a screening approach whose time has come, and holds the potential for decreasing donor self-attrition.

One other issue pertains to the method of questionnaire administration. Computer-assisted self-interviewing (CASI), clearly the way of the future, will not be implemented in most blood centers for several years. Non-computerized screening is still widely used, and donors and blood centers have long sought a donor self-administered questionnaire (SAQ) in favor of the current approach that requires direct oral questioning for many items. Contemporary survey design practice appears to favor SAQs vs. oral questions because of evidence that people are more likely to provide sensitive information in SAQs. In addition, more than 95% of American Red Cross (ARC) blood donors are already screened using a self-administered questionnaire⁴, an approach that was approved by the FDA for routine use in 1998. There is thus a precedent and strong justification for SAQ to be used for all screening of all donors.

IV. Seeking Solutions: The FDA Initiative and the Questionnaire Redesign Project

It is against this backdrop that in the spring of 2000 CBER formally requested that the AABB convene a multi-organizational task force to address many of these issues. At the October 2000 joint AABB and FDA workshop "Streamlining the Blood Donor History Questionnaire," the FDA provided insight for streamlining the UDHQ and developing an abbreviated questionnaire for repeat donors. Explaining that the donor selection process should "contribute significantly towards preventing disease transmission yet not discourage volunteer donations nor result in unnecessary deferrals," the FDA defined specific issues and aspects to consider in the streamlining process. These included consideration of the scientific basis for deferral criteria, effective wording of questions, validation of screening questions, the effect of changes on statistical parameters, development of an abbreviated questionnaire for frequent donors and computer-assisted self-interviewing.²

Many of these goals were shared by the AABB, which in its Task Force charge to “evaluate methods for questionnaire administration”⁵ included an intent to move away from direct oral questioning of donors and toward a written, self-administered instrument.

VI. Task Force Goals

Based on FDA and AABB direction and other needs that were identified during the project, the Task Force’s goals were to:

1. Simplify the wording and questions of the current UDHQ to improve donor comprehension and establish suitability for donor self-administration outside of a CASI environment.
2. Evaluate the revised questions for comprehension, using focus group and state-of-the-art survey design approaches, i.e., cognitive interviewing.
3. Reformat the full-length questionnaire, categorizing items in chronological timeframes and using capture questions.
4. Embed quality assurance tools within the questionnaire to assess donor attention.
5. Develop an abbreviated questionnaire for frequent donors and provide guidelines for its use.
6. Redesign and standardize pre-screening donor educational materials.
7. Develop a “User Brochure” that will explain the use of the new questionnaires to blood centers and donor screeners.

A relevant footnote to the Task Force goals pertains to donor deferral policies. Review and modification of FDA deferral policies was not a goal of the Task Force. Several of these policies have been the subject of vigorous scientific debate over the last several years in FDA Blood Products Advisory Committee (BPAC) meetings and special workshops. Controversial issues debated in these venues include lifetime deferral for a history of hepatitis after age 11, lifetime deferral for male-to-male sexual contact since 1977, deferral for aggregate time spent in the UK and Europe since 1980, and interpretation of criteria for geographic exposure to malaria. Although the Task Force does not necessarily agree with all current FDA deferral requirements, it was beyond the scope of the Task Force’s mandate to make recommendations concerning revision of these policies. Rather, the Task Force objective was to revise existing donor questions to increase the likelihood that optimal information pertinent to carrying out FDA mandated donor deferral policies can be obtained from each individual donor.

V. The Task Force Profile and Resources

A. Task Force Members

Selection of members was driven by the commitment to represent a wide spectrum of constituents and obtain appropriate scientific, methodologic, and other expertise. Members included the FDA, other government agencies, community blood centers, and the source plasma

industry. Particularly notable was the involvement of two health survey design experts and an ethicist acting as a public member. Represented organizations included:

- ~~✍~~ The Food and Drug Administration (FDA)
- ~~✍~~ The Centers for Disease Control and Prevention (CDC)
- ~~✍~~ The National Center for Health Statistics (NCHS) - CDC
- ~~✍~~ The Department of Defense (DOD)
- ~~✍~~ The American Association of Blood Banks (AABB)
- ~~✍~~ America's Blood Centers (ABC)
- ~~✍~~ American Red Cross (ARC)
- ~~✍~~ Plasma Protein Therapeutics Association (PPTA), formerly American Blood Resources Association (ABRA)
- ~~✍~~ Public member (ethicist)
- ~~✍~~ Survey design specialist
- ~~✍~~ Statistician
- ~~✍~~ Canadian Blood Services (CBS - *ex officio* member)

Because requirements for screening and qualifying source plasma donors share similarities with those for volunteer donors, the participation of PPTA was sought. The significant differences between both groups of donors, however, warrant a PPTA screening proposal that will be submitted separately to the FDA.

B. Task Force Resources

Financial resources for carrying out this project were extremely limited, and consisted solely of an \$80,000 funds transfer agreement that was generously provided by the National Heart, Lung, and Blood Institute (NHLBI) to NCHS for cognitive interviews. Aside from this indispensable assistance, virtually all Task Force activities, projects, and surveys were conducted without the benefit of financial support from other governmental agencies, a situation that limited the scope of possible research efforts.

With the support of their respective organizations, Task Force members served on a volunteer basis. *Pro bono* focus group research was sponsored by the Jerome Holland Laboratories of the American Red Cross and carried out by Sharyn Orton, PhD. Survey data tabulation was also provided on a *pro bono* basis by Schulman, Ronca, and Bucuvalas, Inc. The American Association of Blood Banks sponsored three face-to-face meetings, conducted a survey of blood centers, and provided logistical and administrative support. Most communication and discussion took place among Task Force members in dozens of conference calls and hundreds of emails. That so much was accomplished with so few financial resources is a testament to the commitment and dedication of all those who participated in this remarkable effort.

VII. Task Force Products, Rationale, and Methodologies

This section will provide a brief overview of the specific documents developed or produced by the Task Force. All documents are included in tabulated sections, and the reader is referred to these for specific review. The products that will be discussed include:

- A. The revised full-length questionnaire and supporting documentation
 - ~~✍~~ Focus group research summary
 - ~~✍~~ National Center for Health Statistics cognitive interview summary

- ~~///~~ Rationale for revisions of screening questions
- ~~///~~ Rationale for removal of selected non-FDA-required items
- B. The Medication Deferral List
- C. The Abbreviated Questionnaire
- D. Pre-donation Educational Materials
- E. The “User Brochure”

A. The Revised Full-length Questionnaire

The goals for redesigning the full-length questionnaire were to:

- ~~///~~ determine in collaboration with the FDA which questions should be retained, and remove redundant or scientifically non-contributory questions that are not FDA recommended or required.
- ~~///~~ simplify wording and questions, using principles of survey design
- ~~///~~ reformat the document using capture questions and grouping questions in chronological time frames

Retention and Removal of Questions

Most of the current UDHQ items are required or recommended by the FDA, and these were all retained and targeted for simplification and other revisions. A small number of questions, contributed by the AABB but not required or recommended by the FDA, were evaluated for relevance and the contribution to blood safety. Many of these questions were also retained. Questions that were removed were either redundant, contained information best reinforced in educational materials, or were scientifically unfounded.

Simplification of Questions

The goal of simplification of retained items was to reduce each question to the simplest wording possible, with the intent of soliciting target information in the most direct way. The questions were comprehensively reviewed in an iterative process that considered input from numerous sources, including Task Force subcommittees and individuals, survey design experts, the FDA, CDC, AABB members, focus groups, and NCHS cognitive interviews. Input provided at every step was discussed by the entire Task Force.

The chronology and approach for making revisions were as follows:

- ?? Initial review and modification by Task Force subcommittees; the Task Force survey design expert participated in all discussions.
- ?? Focus group evaluation of initially proposed revisions, using a methodology published in peer-reviewed literature⁶. The feedback from these focus groups was used to further modify questions wording and content.
- ?? Submission of revised questions to the National Center for Health Statistics for conducting cognitive interviews.

The Task Force gave strong consideration to focus group and NCHS cognitive interview results. When focus group participants or NCHS interview participants did not reach consensus on a particular issue or wording, the Task Force generally accepted the majority opinions of these groups. In some instances the Task Force deferred to alternatives proposed by the survey design experts or necessitated by regulatory guidance or other compelling input. Particularly, comments

provided by the FDA to the Task Force chair in a letter dated September 4, 2001 were carefully reviewed and also resulted in wording and content changes.

Reformatting the Questionnaire

Prior to submission to the NCHS for laboratory-based cognitive one-on-one interviewing, the simplified questions were arranged in a format that, in general, uses a time-bounded approach. This approach was recommended by the Task Force survey design experts because the current DHQ contains numerous time-based questions of differing intervals that are listed in non-chronological fashion; the mental “time travel” required of donors likely makes recall difficult and is confusing to donors.

Another change in the format makes use of capture questions. These are broad questions that cover general issues like travel, certain medications, and medical conditions. For most kinds of qualifying information, only the capture questions are printed on the questionnaire itself, with necessary follow-up questions for affirmative answers delineated in the User Brochure. After the donor has completed the entire questionnaire, he or she will then be asked the appropriate follow-up questions. This approach permits streamlining for the majority of donors and the obtaining of additional necessary information from others, as appropriate.

A third change in the format is the embedding of two types of quality assurance questions in the document in order to ensure an acceptable level of donor attention. One type of question requires “yes” as the appropriate answer (most questions require “no” as the qualifying response). The other type of question has specific response requirements for gender-based questions. For example, a question targeted to females must be answered “no” by males, rather than left blank. If these quality assurance questions are not answered properly, suggesting an attention lapse or failure to carefully read the question, blood centers must define an appropriate follow-up action; one possibility is for the donor to repeat the entire questionnaire. However, each blood center will determine what the follow-up action should be for a donor who fails the quality assurance items.

Evaluation of the Revised Questions and Supplemental Materials: The NCHS Cognitive Interviews

The revised, reformatted full-length questionnaire, the abbreviated questionnaire, new educational materials and medication deferral list were submitted to the NCHS for evaluation. The methodology employed by the NCHS is recognized as the most appropriate for assessing survey questions, and utilizes methodological experts to perform cognitive, one-on-one interviews of donors and non-donors in a laboratory setting. The NCHS goal was to evaluate the questions and supplemental materials for comprehension and usability, and to identify characteristics that could make a questionnaire difficult to use and/or difficult to answer. Data and recommendations from the NCHS interviews were extensively discussed and served as the basis for further revisions of many questions.

Of particular note is that the focus group and NCHS interviewees identified a key deficiency in the donor screening process: the lack of a definition of “sexual contact.” Currently, nine (9) questions inquire about sexual contact or sex with persons potentially at risk for various infectious agents. However, both the focus group and NCHS subjects repeatedly and overwhelmingly expressed the need to have a definition of sexual contact in the context of blood donation suitability. These observations are supported by a number of additional studies^{7,8,9}.

Therefore, the Task Force has included specific definitions of sexual contact in the educational materials.

The NCHS report makes recommendations about other actions that may enhance the donor screening process. Specifically, the report suggests that blood screeners be provided with lists of aspirin-containing medications and definitions of medical terms such as Chagas' disease, grafts, clotting factor concentrates, etc. According to Task Force members who are affiliated with blood collection facilities, these types of references are already in use. The Task Force recommends that blood centers continue to utilize and update these lists based on locally identified needs. The NCHS report also suggests that lists of countries with bovine spongiform encephalopathy risk (e.g., the United Kingdom and other European countries) and HIV group O-endemic African countries be provided to screeners. The Task Force recommends that, since the US Public Health Service has the best resources for identifying areas of endemic risk, these geographic lists should continue to be developed and updated by the FDA and other Public Health Service agencies and made available to blood centers.

B. The Medication Deferral List

Currently, FDA-designated medications that require temporary or permanent deferral are listed on the UDHQ. As new drugs requiring FDA deferral are identified, they are added to the questionnaire, increasing length and complexity and necessitating the revision and reprinting of questionnaire forms. To address this situation, the Task Force has introduced the concept of a "Medication Deferral List." Donors will review the medication list, which is a companion document to the questionnaire, and respond to a capture question about whether they have taken any of the medications on the list. After completion of the questionnaire by the donor, any affirmative answers will be followed up to obtain further information.

The Medication Deferral List contains two sections. The upper section specifically lists the medications and the main indications for prescribing and must be reviewed by the donor. The lower section is for donor informational purposes, and lists the rationale for deferral.

Deferral criteria for medications not on the medication deferral list will continue to be locally defined. Centers will have the option of adding medications to the list to adhere to local policies or procedures.

C. Abbreviated Questionnaire for Frequent Donors; Definitions; Guidelines

All donors, including frequent donors, are currently required to answer all UDH questions, even those that pertain to one-time historical events that could never recur (e.g., the use of human pituitary-derived growth hormone, which was no longer available after the early 1980s). Donors and blood centers have long desired an abbreviated questionnaire for frequent donors. In 2000 the FDA approved an abbreviated version for one blood center, and currently is reviewing another. In the October 2000 workshop on streamlining the questionnaire, the FDA communicated its support for an abbreviated version for frequent donors and provided suggestions for developing such a document¹⁰.

The Task Force has developed an abbreviated questionnaire for frequent donors, has proposed a definition of "frequent donors," and devised guidelines for its use, based on direction from the FDA. The main features of the abbreviated version are that it eliminates the repetition of one-time event questions, and is geared to identify recent changes in health, behavior, and travel information. A sample of subjects evaluated the abbreviated version in the NCHS interviewing

process, and feedback is provided in the NCHS summary. This truly streamlined version is expected to be welcomed and well-received by those donors to whom usage criteria apply, and could make a major difference in the perception of the donation process for many current and prospective donors.

D. Donor Pre-screening Educational Materials

The concept of providing donors with pre-screening educational materials was devised by the AABB in 1984¹¹, and the FDA has required it since 1990¹². The intent was to educate donors about HIV and AIDS with the goal of prompting self-deferral or at least questioning of blood center staff by those to whom such information might apply. Since then, the educational materials have played an increasingly significant role in familiarizing donors with other deferrable risks and the donation process. A Task Force review of educational materials from more than twenty blood centers, including the American Red Cross which uses standardized materials, showed considerable variation, however.

Because the educational materials constitute an informational tool with which donors are familiar, the Task Force is advocating that renewed emphasis be placed on them and that they be standardized. This Task Force-designed document emphasizes the importance of accuracy and honesty in responding to screening questions, has defined sexual contact, more clearly explained HIV and AIDS information, and detailed the donation process. In addition, because information contained in some previously AABB-generated questions is being transferred to the educational materials, the Task Force is recommending that the educational materials be standardized; blood centers would be permitted to add additional information, but not delete or rearrange the materials once approved by the FDA.

E. The User Brochure

When approved by the FDA, the new donor screening instruments – the full-length and abbreviated versions and the educational materials – will represent a significant change for blood centers. In order to facilitate understanding and use of the new materials by blood centers and donor screeners, the Task Force has developed a “User Brochure.” This document details how the questionnaires should be administered, explains the concept of capture questions – already in use by blood centers – and offers suggested follow-up for affirmative responses to capture questions. Its flow-charted format, based on information-mapping models, is expected to provide ease of use and enable rapid adoption of the new screening materials.

Methods of Administration

The User Brochure addresses the manner in which the questionnaires should be administered. Simplification and donor comprehension have been a major goal of the project in order to maximize the quality of donor information and to facilitate the adoption of a self-administered questionnaire. The discussion that follows details the rationale of the Task Force for recommending that the questionnaires be self-administered by donors.

Self-Administered Questionnaires and Direct (Face-to-Face) Oral Questioning

AABB blood center survey data show that the direct oral questioning of donors who have already completed a written questionnaire has been cited by some centers as a source of donor

complaints. Currently, most non-American Red Cross (ARC) blood centers utilize a donor self-administered written questionnaire but are required to ask the HIV risk questions in face-to-face interviews¹³. Recently issued FDA questions regarding CJD/vCJD¹⁴ and xenotransplantation¹⁵ also recommend direct oral questioning. However, a precedent for allowing donor self-administration of a written questionnaire was established when the American Red Cross received FDA approval for such an approach, provided that the donors are given an opportunity to ask additional questions or seek clarification. This FDA-approved ARC method, which showed no apparent increase in infectious disease incidence or prevalence rates,¹⁶ has been in general use since 1998. To date, incidence and prevalence data have not shown a compromise in blood safety as a result of utilizing this alternative screening methodology.

The interest in using direct questioning of blood donors vs. Self –Administered Questionnaires (SAQs) for HIV risk questions originated in an early study that showed a statistically significant difference in overall deferrals and HIV risk deferrals in blood donors screened with direct questions. However, it was observed that, in general, first-time and occasional donors were more likely than frequent donors to pay attention to SAQs¹⁷. In a later study that compared blood donor interview modes, donors seemed more likely to provide HIV risk information in a face-to-face interview vs. a self-administered format. However, the observed overall decline in HIV seroprevalence was not statistically significant, had been observed prior to implementation of direct questioning, and was likely not attributable to direct questioning¹⁸. It is also likely that public awareness of HIV risk factors has increased in the decade since the first study was undertaken¹⁷, possibly diminishing or even negating the potential of direct questioning to identify individuals with risk.

Outside the blood donor screening arena, there is considerable evidence that people disclose less information of a personal nature - such as use of alcohol and illicit drugs, sexual behaviors, and mental health - in the presence of an interviewer. Examples include studies by Aquilino demonstrating greater likelihood to discuss a history of depression¹⁹ and admit to use of illegal drugs and alcohol in SAQs compared to other modalities²⁰; and Tourangeau et al, showing a significantly increased likelihood to report number of sexual partners, sexually transmitted diseases, and condom use in SAQs vs. face-to-face interviews²¹.

Input from Task Force and NCHS survey design experts also generally favors SAQs over face-to-face interviews for several reasons. Interviewers can introduce errors into the data collection process, some of which can be avoided by self-administration. For example, even well trained interviewers can start to anticipate responses to questions that have little response variation, and they may also introduce variety into question administration. In addition, respondents are more likely to focus on questions that they themselves read vs. those that are read to them.

Viewed alone or in concert, survey design literature and the experience of survey design experts suggest that any perceived advantage of direct questioning over SAQ in identifying risks among blood donors may no longer be as great as originally perceived. *It is particularly important and relevant to this discussion to note that the cognitive interviews performed by NCHS assumed a self-administered survey. This offers reassurance that a SAQ would “work” in a blood donor screening milieu.* Conversely, there is no guarantee that an interviewer-administered questionnaire would be as effective. For these reasons, the Task Force recommends in the User Brochure that the questionnaires be self-administered by blood donors, without the use of direct questioning by blood center staff. However, it does recommend that blood center staff be readily available to assist donors and provide clarification when needed. Blood centers that wish to continue using direct questioning will have that option.

Blood centers that have implemented CASI will find that the capture-question approach, questionnaire format, and simplified questions of both the full-length and abbreviated questionnaires will be easily integrated into a computerized methodology. However, it should be noted that CASI is in its nascency, and only now is being implemented in a handful of blood centers. Non-CASI screening will continue to be used for the foreseeable future until CASI software is further refined and validation guidelines are more clearly delineated by regulatory and standard-setting agencies. Therefore, the User Brochure focuses primarily on self-administration of the questionnaire by donors.

VIII. The Blood Donor Screeners' Survey: Field Testing the New Materials

The Task Force determined that the new screening and accessory materials should ultimately be evaluated by a cohort of blood center staff who perform eligibility screening of prospective donors. These individuals, referred to as blood donor historians or screeners, were selected to cover a range of experience, ages, and genders. Thirteen screeners from five blood centers reviewed the near-final educational materials, the full-length and abbreviated questionnaires, the medication deferral list, and the user brochure. Specific areas of interest to the Task Force were the format, ease of use, and understandability of the documents.

Using a survey developed by the NCHS, the participants were asked to respond on a rating scale to statements about each document. They were also asked to compare their current questionnaire to the full-length questionnaire. The data indicated strong support and enthusiasm for the new documents, suggesting that the Task Force had met its goals in producing materials that would be relatively easy to administer and would be well-received by donor screeners.

IX. Communicating with Constituents

As important as the redesign process, so has been the Task Force's effort to communicate their work, thinking, and progress. The process has been open, public, and widely publicized. The Task Force members have effectively engaged in bi-directional communication with their respective organizations. Documents have been given to the FDA for internal review, and FDA input on all issues has been consistently sought. Updates have been provided in the past year-and-a-half in numerous meetings sponsored by the AABB, ABC, ARC, PPTA, and the FDA. Most of these organizations have regularly provided information to their members in newsletters and other publications. In the past six months drafts of Task Force documents have been posted on the public section of the AABB Web site for review and comment by the public and AABB members. Finally, and perhaps most critical, the Task Force's approach and document drafts were reviewed by the FDA's Blood Products Advisory Committee (BPAC) in June 2001, and received BPAC endorsement.

X. Implementation

Following the FDA's review and approval of the redesigned screening products and processes, the AABB will disseminate the materials and information about usage to members through teleconferences, meetings, publications, and its Web site. Blood and plasma centers will be responsible for familiarizing themselves with the new documents and training their staff. The AABB will make its resources available to provide assistance as needed.

While the current FDA position is that the new questionnaires and materials will not be recommended or required, the Task Force requests that the FDA strongly encourage blood

centers around the country to implement these documents. The timeframe for implementation should be established in discussions between the AABB and the FDA.

XI. The Next Steps: Formulation of New Questions

The AABB will be establishing a standing donor history questionnaire (DHQ) committee to continue working with the FDA in the question formulation process. The Task Force strongly recommends that the FDA adopt a new approach, modeled after that introduced by the Task Force, for devising and evaluating screening questions. The Task Force also recommends that the FDA continue to consider the impact that new questions will have on blood availability, donor motivation, and the complexity of the screening process.

XII. Computer-Assisted Self-Interviewing (CASI)

During the next several years, CASI will assume a dominant role in the donor screening process. The potential benefits of this modality are legion:

- ✍ Standardization of donor screening within a blood center and among blood centers.
- ✍ Elimination of missed questions
- ✍ Improved data capture
- ✍ Efficiency
- ✍ Multiple language options
- ✍ Visual, auditory presentation options
- ✍ Optimal for algorithmic and capture question approaches
- ✍ Optimal for abbreviated versions

The expense and task of validating and implementing CASI programs present formidable challenges to blood centers. The Task Force recommends that the FDA make this process as inviting and smooth as possible by providing achievable and unambiguous direction. The FDA can facilitate the transformation to CASI by conducting rapid review of programs under evaluation and expediting its review of blood center procedures and plans. The AABB should, through its future DHQ committee, play a role in promoting the adoption of CASI and consider the timely development of standards to guide blood centers in their efforts.

XIII. Blood Safety and the Revised Donor Screening Materials

In the early stages of the project, the FDA suggested that changes made in the screening process be considered for predictive value, sensitivity, and specificity². Although there are several theoretical ways to obtain such data, all have significant limitations. The most direct method would be to measure infectious disease marker rates in donors deferred by a newly implemented question and compare this with the rates using the older version of the question. However, since no samples are drawn from deferred donors, this approach is unworkable unless new informed consent and logistical procedures were to be put into place. Even then, given the anticipated non-specificity of most screening questions, it would require a very large sample size to document any difference.

A second approach would be to document a decrease in infectious disease marker rates in eligible donors following the implementation of a new question. However, current serologic and nucleic acid testing have improved detection of infectious agents to the point that it would be exceedingly difficult from a statistical standpoint to determine if any decrement in infectious

disease rates would be observable. Even if it were possible to ascertain differences, the process would require such a lengthy surveillance period and evaluation of so many donations that this kind of undertaking would almost certainly be logistically and financially prohibitive. It should be noted that the questionnaire redesign process was an unfunded initiative, except for the monies that were contributed by NHLBI for the NCHS cognitive interviews. Thus, Task Force research to evaluate changes in statistical parameters would not have been possible, something of which all parties have been aware during the entire process.

Pre-donation screening is one of the pillars of blood safety. The goal of screening is to obtain donor information that is as accurate, honest, and relevant as possible. This process can only be optimized if donors comprehend the questions and answer honestly. The Task Force believes that donor comprehension – and ultimately blood safety - will be improved through the rigorous and methodical process that was applied for simplifying the questionnaire and assessing comprehension. The methods used by the Task Force – input from survey design experts, focus groups, and NCHS cognitive interviews – encompass an approach that has never before been used for formulating questions. Historically, since there has not been a model for evaluating questions, the changes made by the Task Force represent a major and significant advance in donor screening and can only enhance blood safety.

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